

# Direct Consumer Marketing of High Cost Radiology Tests

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# The Issue

- High cost radiology tests are being directly marketed to consumers to screen for
  - Malignancies (e.g., lung cancer via whole body CT)
  - Coronary artery disease (EBCT)
- Value of these technologies is unproven
  - Concern regarding false positive rates (and false negative rates)
  - No evidence that they improve patient outcome
- Consumers being asked to pay out of pocket
- Tests sometimes offered at low cost by health care organizations– with expectation that follow-up tests will be covered by insurance.

# EBCT for Coronary Disease Detection

- EBCT can detect calcium deposits in coronary arteries – which are present in most patients with coronary disease
- Higher calcium scores = higher risk for atherosclerosis = higher risk for heart attack
- BUT ...
  - Overall risk for asymptomatic people with coronary disease is low
  - No study has shown that treatment of high calcium scores improves outcome
  - High false alarm rate



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# What Do EBCT Results Mean?

- Low calcium score – 99% chance of no cardiac events over next year
- High calcium score – 1-5% risk
- If you do not have obstruction in your coronary arteries, what are the chances you will have a worrisome calcium score? 50% to 70%

# Implications

- Most people do not get the reassurance they seek.
- Many patients get further testing/treatment:
  - Exercise tests
  - Cardiac catheterization
  - Angioplasty or bypass graft surgery
- Bottom line: American Heart Association and American College Cardiology do not recommend this test. (Circulation 2000;102:126-40)

# Whole Body Scanning Using Computed Tomography (CT)

Last Updated: 04/17/2002

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Currently some medical imaging facilities are promoting a new use of computed tomography (CT), also called computerized axial tomography (CAT) scanning. This use is referred to as whole-body CT scanning or whole-body CT screening, and it is marketed as a preventive or proactive healthcare measure to healthy individuals who have no symptoms or suspicion of disease. **At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death.** Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause.

Public health agencies and national medical and professional societies-the [American College of Radiology](#), the [American College of Cardiology / American Heart Association](#), the [American Association of Physicists in Medicine](#), and the [Health Physics Society](#) -do not recommend CT screening.



FDA has published a brochure titled:  
**["Full-Body CT Scans - What You Need to Know"](#)**



**CT** is a diagnostic imaging procedure that uses x rays to obtain cross-sectional images of the body. Since its introduction and rapid adoption into medicine in the mid-1970s, CT has become recognized as a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.





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Brain Scan  
Heart Scan  
Lung Scan  
Bone Density Scan  
Carotid Artery Scan  
Body Scan F.A.Q.

Body Scan Methods :

EBT Scanning  
Spiral CT Scanning  
PET Scanning  
Open MRI  
MRI  
Helical CT

Diseases Screened for :

Lung Cancer  
Heart Disease  
Colon Cancer

About the Technology :

Imatron (from GE)

## Body Scan Methods

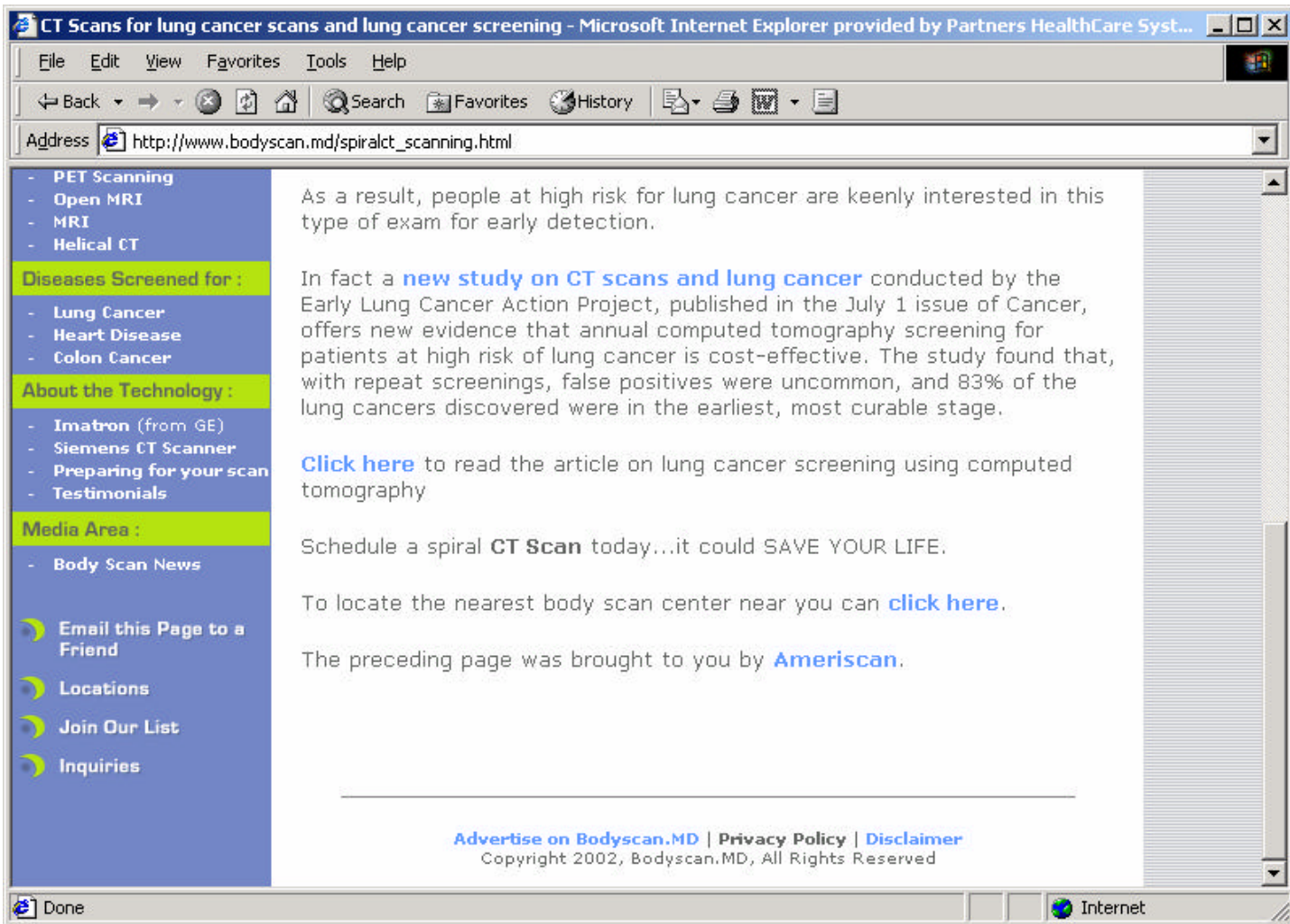
### CT Scans

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Low-dose Spiral **CT scans** are emerging as one of the most promising tools for lung cancer scans. The spiral **CT scan** is a painless procedure in which a special computerized tomography imaging machine rotates rapidly around the body, taking over one hundred pictures in sequence. The scan is so sensitive that it's possible to detect nodules that are too small to be seen on a conventional x-ray, which make it an excellent tool in lung cancer screening.

As a result, people at high risk for lung cancer are keenly interested in this type of exam for early detection.

In fact a [new study on CT scans and lung cancer](#) conducted by the Early Lung Cancer Action Project, published in the July 1 issue of Cancer, offers new evidence that annual computed tomography screening for patients at high risk of lung cancer is cost-effective. The study found that, with repeat screenings, false positives were uncommon, and 83% of the lung cancers discovered were in the earliest, most curable stage.



# Do They Save Lives?

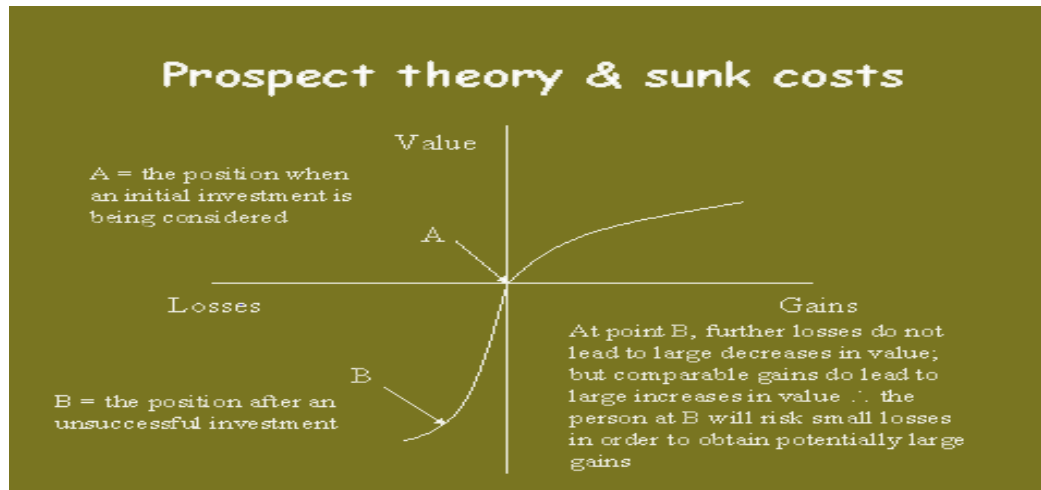
- Not proven in any study
- Chest x-rays do NOT prevent death from lung cancer – they just lead to earlier detection.
- Tumors have millions of cells by the time they are 1-2 mm in diameter – and some research indicates that they have already metastasized if they are “programmed” to do so.
- Proponents say it would be unethical to ask people to wait; Opponents say it is unethical to ask people to pay for unproven technology.

# False Reassurance

- Negative CT can easily miss small tumors
- Some cancers are not visible by routine CT unless contrast agents are given – but contrast agents carry small (~1%) risk of reactions, and are expensive.
- Physician concern: Patients may continue smoking, etc., because they believe they are “getting away with it.”

# Can Patients Be Informed Consumers of Such Tests?

- Physicians and celebrities are advocating testing in advertisements
- Patients (and physicians) have difficulty putting risks in perspective



# What Do Physicians Do?

- Email poll of 141 internists and 26 cardiologists at MGH and BWH.
- “Have you undergone CT to screen for cancer or EBCT to screen for coronary disease?”
- “If so, did you pay with your own money?”
- Results: No internists had been tested. 2 cardiologists had had EBCT, but neither paid. One indicated that he would have paid.

# MD Comments on EBCT

- JR – “I would not have it done even if it was covered by insurance. It’s hype. I also discourage my patients from having it done if they ask.”
- RG – “No... I was asked by my wife’s rich uncle in Argentina whether he should invest .. I told him a good plan would be to get in and then make sure there was a clear exit strategy once people figured out the critical limitations.”
- HG – “NO, I can’t see use for it save to generate anxiety and more business for ETT lab which would be good from purely commercial standpoint.”
- JL – “Absolutely not. This test is not ready for prime time.”